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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,880	12/12/2003	John P. Fruehauf	02-1270-A	1031

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,880	FRUEHAUF, JOHN P.	
	Examiner	Art Unit	
	LEI YAO	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 22-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/27/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment and Arguments

The Amendment filed on 1/22/2009 in response to the previous Non-Final Office Action (7/22/2008) is acknowledged and has been entered.

Claims 1-43 are pending.

Claims 1-19, and 22-39 have been previously withdrawn for non-elected invention.

Claims 20, 21, 40-43, drawn to amethod for identifying a tumor resistant to taxane drugs by determining expression of one or plurality of genes, are under consideration.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 1/27/2009 are/is reviewed by the examiner, however, the publications listed in the IDS fails to comply with the provisions of 37 CFR 1.97-1.98 and MPEP 609 because the items do not contain the titles for publications. It has been placed in the application file, but the information referred to herein has not been considered as to the merits. See 37 CFR1.98, (b)(5) for details.

Rejections Withdrawn

The rejection of claims 20, 21, and 40-43 under 35 U.S.C. 112, first paragraph, as requiring SEQ ID NOs for related GenBank Accession Nos in the claims is withdrawn in view of amending the claims including the SEQ ID NOs and 132 declaration by W.

Ricketts indicating the association of the SEQ ID NOs in the sequence listing with the submitting dates in GenBank Accession Nos.

Rejection Maintained and Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 20, 21, and 40-43 remain rejected under 35 U.S.C. 112, first paragraph as a New Matter because the specification does not provide sufficient support for the GenBank Accession Nos added in the amended claims.

Applicant argues that the names in the pending claims are known and were known to be associated with GenBank Accession Numbers (bridging page 11- 12) and GenBank Numbers were added to the pending claims to remove any ambiguity with regard to the identity of these genes (page 13, line 8+).

In response, Applicant is reminded that amending claims or specification to broaden or narrow down the originally claimed invention would be subjected to a new matter rejection. In this case, the claims as originally presented recite names that could be represented by different sequences, such as variants of a gene or a gene in different species, mouse or human etc. The later submitted each GenBank accession number would present only one gene from one species. For example, added GenBank No.

AF458589 represents only human myosin phosphatase target subunit 1 variant, PPP1R12A, not other variants from other species. When searching originally claimed myosin phosphatase target subunit 1 in the nucleotide database NCBI results in 31 genes including PPP1R12B and Ppp1r12a etc. Thus, currently claimed invention with GenBank Nos has different scope as compared to the originally claimed invention.

Applicant further argue that the 132 declaration submitted by Dr. W. Ricketts stating the correspondence of each of the claimed genes with the specific dates of submitting or updating the sequences in the NCBI database. The declaration is considered and sufficient to overcome the rejection of 112 1st written description (page 3-5 of the Office action, 7/22/2008), not the new matter rejection above.

Enablement

Claims 20, 21, and 40-43 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection is based on that neither the art of record nor the specification has provided any teaching to determine the taxane resistant breast tumor or cells by comparing gene expression between tumor and non-tumor cells when the tumor has not been exposed to any taxane drug.

Response to Applicant's Argument:

On page 16, line 6+, Applicant argues that cell resistance and sensitivity to taxane drugs can be an intrinsic property of cells and states that this intrinsic property is explored in Example 2 where the genes with differential expressions in taxane resistant and sensitive cells are identified using the EDR assay show in Table III. Applicant further describes the EDR assay (extreme Drug Resistance) as that tumor cells are exposed to a cytotoxic concentration of taxane for a period of 4 days, where the 4-day period is not sufficiently long to induce gene expression (Specification p19-20). Genes identified by such EDR assay reflect intrinsic resistance of these cells (page 16, last lines of para 2). Applicant further describe the cell used are tumor cell and endothelial cell in such assay (para 3, page 16).

In response, the described experimental process for the claimed method does not provide objective or convincing evidence for the claimed method because the process is not performed and understood as the way of one skilled in the art. First, many genes listed in the claims have not been recognized in the art as specific markers for tumor resistant cells, they are expressed in the normal, tumor, and drug resistant tumor cells. For example, plasminogen activator and urokinase receptor are detected being expressed in many tumor cells without a treatment. Second, inducing resistance to taxane drugs depends time exposed, dosage of the drug used, and tumor or cell types tested etc. For example, Mechetner et al (Clinical Can Res, vol 4, page 389-398, 1998, provided 5/2006) describe EDR assay and teach that breast carcinoma has not been thought to belong to the group of tumor derived from tissues that intrinsically

express multidrug resistance (MDR) P-glycoprotein, such as colon and renal cell carcinoma (page 396, col 2). Further, Mechetner et al describe EDR assay by incubating breast cancer cells under standard cultured conditions for 4 days in the presence and absence of a taxane drug, and testing MDR P-glycoprotein expression. The result shows 30% MDR P-glycoprotein expressed in the treated cell compared to 11% in the untreated cells (page 393, table 2). Mechetner et al comment that the difference in P-glycoprotein expression between untreated and treated was highly significant. Does this indicate that 4 day exposure of taxane drug could sufficiently induce a gene expression, while Applicant argues that it does not? One skilled in the art would not consider that such expression is a intrinsic property.

Third, the Office does not understand why the instant application uses endothelial cell, not the same type non-tumor cell (normal breast cell), as non-tumor cell control to compare to the tumor cell in such assay. It is well accepted concept in the field that tumor developing resistance to a taxane drug is due to expression of gene(s) in the treated tumor cell after exposure of the taxane drug. The gene expression patterns between tumor cell and normal endothelial cell are distinct. Comparing the gene expression levels between the two different cell types to determine the sensitivity of a cell to the taxane (table III) does not convince the Office and one skilled in the art that claimed invention of identifying tumor resistant to taxane is enabled and could be practiced by any one of skilled in the art. It would be appreciated if Applicant could provide objective evidence or more data that sufficiently support Applicant's position, resistant to taxane drug is intrinsic property of a tumor.

Thus, Applicant's argument has not been found persuasive, and the rejection is maintained currently.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao/
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643